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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,744	08/18/2000	Brian F. Tack	IOWA:026US	7819

7590 12/15/2003  
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EXAMINER
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SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/642,744

Applicant(s)

TACK ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 32-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,32 and 33 is/are rejected.
- 7) ☐ Claim(s) 34-55 is/are objected to.
- 8) ☒ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 10/02/2003 has been entered.
2. Applicants' substitute preliminary amendment following request for continued examination of 11/10/2003 is acknowledged. Claims 2 and 4-31 have been canceled without prejudice. Claims 32-55 have been added.
3. Claims 1, 3 and 32-55 are pending.

***Prior Citations of Title 35 Sections***

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

***Objections Maintained***

5. Objections to the drawings made in paragraph 6 of the office action mailed 7/29/2002, paper #16 are maintained. No amendments to the drawings were submitted. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Rejections Withdrawn***

6. Rejection of claims 1 and 3 under 35 U.S.C. 112, first paragraph made in paragraph 11 of the office action mailed 3/26/2003, paper #19 is withdrawn in view of applicants' amendments.
7. Rejections of claims 1 and 3 under 35 U.S.C. (102) b made in paragraphs 8, 9 and 10 of the

office action mailed 7/29/2002, paper #16 is withdrawn in view of applicants' amendments.

*New Grounds for rejection*

*New Matter Rejection*

8. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims now include the newly added limitation "12-37 residues". However, there appears to be no descriptive support in the instant specification for this added limitation. 37 CFR 1.121

requires that an amendment to the claim must have antecedent basis in the original disclosure.

Therefore the new limitation in the claim is considered new matter. In re Rasussen, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step or a compound from a disclosure. See MPEP 608.04.

*Claim Rejections - 35 USC § 112 Second Paragraph*

9. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation "the sequence". There is insufficient antecedent basis for this limitation in the claim.

*Claim Rejections - 35 USC § 102*

10. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Panorama Research Inc. (WO 94/02589).

Claims 1 and 3 are drawn to isolated antimicrobial peptides comprising an amino acid sequence.

Panorama Research Inc. teaches isolated antimicrobial peptides comprising the amino acid sequence identical to amino acid sequence (SEQ ID NO 19) of the claimed invention (see abstract, page 59, claims and attached sequence alignments Accession number AAR45671). Panorama Research Inc. also teaches pharmaceutically acceptable carrier (see page 18 and claim 11). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. Claims 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahoney et al. (FEBS Letters, Vol.377, pp. 519-522, 1995) prior art already made of record in applicants' 1449 and PTO 892.

Claims 32 and 33 are drawn to antimicrobial peptide consisting of the amino acid sequence having SEQ ID NO 27.

Mahoney et al. teach antimicrobial peptide consisting an amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see abstract, fig 2 and sequence alignments Accession numbers S68411 and S68412). Mahoney et al. also teach sterile water as pharmaceutically acceptable carrier (see material and methods). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Bagella et al. (FEBS Letters, Vol.376, pp. 225-228, 1995) prior art already made of record in applicants' 1449 and PTO 892.

Claims 32 is drawn to antimicrobial peptide consisting of the amino acid sequence having SEQ ID NO 27.

Bagella et al. teach antimicrobial peptide consisting the amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see abstract, fig 1, section B and sequence alignment Accession number S68228). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of

prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

13. Claims 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Merluzzi et al. (Peptides, Vol.261, pp. 639-640, 1996) prior art already made of record in applicants' 1449 and PTO 892.

Claims 32 and 33 are drawn to antimicrobial peptide consisting of the amino acid sequence having SEQ ID NO 27.

Merluzzi et al. teach antimicrobial peptide consisting the amino acid sequence identical to amino acid sequence (SEQ ID NO 27) of the claimed invention (see page 639). Merluzzi et al. also teach water as pharmaceutically acceptable carrier (see page 640). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i. e., that the product of prior art does not possess the same material structure and functional characteristics of the claimed product). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

### *Conclusion*


14. No claims are allowed.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Khatol Shahnan-Shah, B.S. Pharm, M.S.

Biotechnology Patent Examiner

Art Unit 1645  
December 9, 2003

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER